REMARKS/ARGUMENTS

Reconsideration of the above-identified application respectfully requested.

In light of the Examiner's Advisory Action mailed July 21, 2003, and subsequent telephonic communications with the undersigned, the independent claims have been recast as product-by-process claims. No new matter is added by this amendment and entry of the amendment is respectfully requested. Accordingly, Applicants assert that no claims have been narrowed with the meaning of *Festo* (*Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 US 722, 112 S.Ct. 1831, 152 L.Ed.2d 944, 62 USPQ2d 1705 (2002)).

Applicants have made clear in the specification and through the claims under consideration that the instant invention is neither anticipated by nor rendered obvious from any prior art, either alone or in combination. The Examiner states in explanation for each of the rejections of record that "[a]pplicants have not gone on the record stating unequivocally that proteins less than 50 kDa in size are specifically excluded in the instant invention." (emphasis in original). It is noteworthy that the Examiner points to no passage in any of the cited art that specifically discloses or claims the Applicants' invention of a therapeutic factor possessing a size of greater than 50 kDa.

Both the specification and the claims make clear that Applicants consider their invention to consist essentially of *only* those components of the cellular supernatant from stimulated cells that are selected by an ultrafiltration membrane with a size exclusion limit of 50 kDa. Those components of the supernatant of cells stimulated according to the Applicants' invention that are not selected by an ultrafiltration membrane with a size exclusion limit of 50 kDa are excluded from the claimed invention. That the factor may be a multimer based on a monomer of less than 50 kDa size is irrelevant, since the active (and claimed) form of the material is greater than 50 kDa in size. Thus, Applicants' claims have also been limited to those components of the cellular supernatant from stimulated cells that do not pass through an ultrafiltration membrane with a size exclusion limit of 50 kDa. The claim language chosen by Applicants, *viz.*, "consisting essentially of", limits the scope of the claims to the specified materials or steps "and those that do not materially affect the basic and novel characteristics" of the claimed invention. *In re Herz*, 537 F.2d 549,551-552, 190 USPQ 461, 463 (CCPA 1976). Applicants, then, believe that the claims make clear that *only* those components from mitogenically stimulated lymphocyte cells of greater than 50 kDa are part the claimed invention.

The Advisory Action states, *inter alia*, that a "product-by-process claim, which is a product claim that defines the claimed product in terms of the process by which it is made, is proper." Amended claims 1 and 57 now are cast as product-by-process claims that limit the "factor" claimed to consist only of components have a molecular weight greater than 50 kDa. That fact that weight factors less than 50 kDa "are not detrimental to the function of the 'factor'", as alleged by the Examiner, is disputed for two reasons. First, it is Applicant that "the subject matter which the applicant regards as his invention" (35 U.S.C. § 112) and Applicant has chosen to exclude components have a weight of less than 50 kDa. Second, the data in the above-identified application argues against the Examiner's statement, *to wit*, Example 1 and Tables 1 and 4A; Example 5, Table 25; and Example 6, Table 27. Each of these tables report data to the effect that the presence of the greater than 50 kDa fraction displays superior results (*e.g.*, anti-viral activity and anti-tumor activity) compared to the less than 50 kDa fraction and greater than the entire supernatant of Triozzi '381. Yes, the entire supernatant.

Thus and contrary to the Examiner's statement, the presence of the components in the less than 50 kDa fraction do have a detrimental affect on the activity of the factor. Inasmuch as Applicants have chosen to exclude such less than 50 kDa fraction, which is their right and which is supported by the data, renders the amended claims patentable. Such results cannot have been fathomed from the prior art even with the best of reading of the prior art.

Conclusion

In light of the novel and nonobvious inventive matter disclosed by the application, Applicants kindly request the Examiner withdraws the rejections of record. Accordingly, in view of the Applicants' current and previous amendments to the claims and remarks submitted herewith, allowance of all claims and passage to issue of this application respectfully is requested. If an allowance is not forthcoming, please enter this amendment for purposes of appeal. Should any questions remain, the Examiner respectfully is invited to telephone the undersigned.

Respectfully submitted,

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CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this Response After Final (BOX AF) is being sent onAugust 6, 2003, by facsimile to the Honorable Commissioner of Patents at facsimile number 703-872-9307 as an after final communication.

Jane Keeney